APR 26 2005

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510(k) Summary of Safety and Effectiveness

510(k) Notification K043380
Date: April 21, 2005
Submitter:
Monebo Technologies, Inc.
1800 Barton Creek Blvd
Austin, Texas 78735-1606

Contact Person:
Dale J. Misczynski
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Trade/Device Name: Monebo Automatic Arrhythmia Detection Software Library, Version 1
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS

Predicate Devices:

The Monebo Automatic Arrhythmia Detection Software Library, Agilent and Brentwood ST/AR predicate are software only devices that monitor cardiac function. Table 1 compares the features of the Automatic Arrhythmia Detection Software Library to predicate devices.

Feature	**Automatic Arrhythmia Detection Software Library**	**Agilent 510(k) K003621**	**Brentwood 510(k) K013717**
Heart rate determination for non-paced adult	**NO**	**YES**	**YES**
Non-paced ventricular arrhythmia calls for adult patients	**YES**	**YES**	**YES**
Ventricular ectopic beat detection	**YES**	**YES**	**YES**
Patient Populations	**Adult**	**Adults, Pediatric, Neonatal**	**Adult**

Test Results

The bench test results of the software using AHA and MIT-BIH databases are show in the table below:

Summary results of AHA and MIT testing

Database	QRS Se	QRS +P	VEB Se	VEB +P
AHA	99.56	99.9	82.49	95.65
MIT-BIH	99.45	99.45	87.03	87.76
NST	91.56	85.66	81.79	53.19

Device Description:

The Monebo Automatic Arrhythmia Detection Software Library is an "object library". An object library is a collection of callable functions that have been complied (or assembled) into machine code or IDL code of the computer on which they execute. The Automatic Arrhythmia Detection Software Library consists of a basic application for viewing, analyzing and annotating ECG data and callable object library built on the Microsoft™ .Net framework. An application software program can be written to invoke some or all of the functions in an object library.

The Monebo Automatic Arrhythmia Detection Software Library provides ECG signal processing, QRS detection, QRS feature extraction, and ventricular ectopic beat detection for up to 12 leads of captured ECG data.

Monebo will compile the Automatic Arrhythmia Detection Software Library specified by an ECG analysis device manufacturer. An object library will be created and delivered to the device manufacturer, who can then integrate it into application software for their ECG analysis. The device manufacturer will be required to submit a 510k with the specific requirements for that device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 26 2005

Monebo Technologies, Inc.
c/o Mr. Dale J. Misczynski
President
1800 Barton Creek Blvd.
Austin, TX 78735

Re: K043380
Trade Name: Monebo Automatic Arrhythmia Detection Software Library, Version 1
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: March 18, 2005
Received: March 21, 2005

Dear Mr. Misczynski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043380

Device Name: Monebo Automatic Arrhythmia Detection Software Library

Indications For Use:

The Automatic Arrhythmia Detection Software Library is intended for use by qualified medical professionals for assessing historic ambulatory ECG data. The product allows downloading and analyzing data recorded in compatible format by Holter or Event monitoring devices. The Automatic Arrhythmia Detection Software Library provides ECG signal processing and analysis on a beat by beat basis, QRS and Ventricular Ectopic Beat detection, and QRS feature extraction.

The product can be integrated into computerized ECG monitoring devices. In this case the medical device manufacturer will identify the indication for use depending on the application of their device.

Prescription Use __√____ AND/OR Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) .

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043380